

REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claims 1, 2, and 4-27 are currently pending in this application. Consideration and entry of this response is respectfully requested.

DOCKET NUMBER

Applicants respectfully request that the docket number for this application be changed from 13115 to "API-02-06-US", if possible. Applicants appreciate the Examiner's assistance with this request.

REJECTIONS UNDER 35 U.S.C. 103(a)**A. REJECTION OF CLAIMS 1, 2, 4-14 AND 20**

Claims 1, 2, 4-14, and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hurpin in view of Hodge, Lehner, and U.S. Pat. No. 6,127,116 ("Rice"). Applicants have carefully reviewed this Office Action and respectfully disagree with the Examiner's conclusions. As the Examiner has not clearly identified the factual foundation for a reasonable expectation of success in the cited art, Applicants respectfully submit that the Examiner has failed to make out a prima facie allegation of obviousness under 35 U.S.C. § 103, as indicated below.

Applicants note that on page 3, line 3 of the Office Action, the Examiner refers to Dow et al. This reference was previously disqualified, and Applicants believe it was referred to in error and that the Examiner meant to refer to Rice. In the event Applicants are incorrect, it is once again argued that Dow is not a proper reference with which the instant claims may be rejected as obvious.

The Examiner alleges that Hurpin teaches intrasplenic administration of an antigen and Hodge teaches a prime-boost immunization methodology, but admits that "... neither ... specifically teaches the administration of the antigen to the lymph node or directly into the lymph node." The Examiner then turns to Rice to satisfy the deficiencies of Hurpin and Hodge, stating that Rice teaches "... that many routes of administration can be used to administer protein or nucleic acid antigens to a mammal in order to induce an immune response, one preferable route being direct administration into lymph nodes ...

. .” The Examiner also alleges that Lehner provides the motivation to administer vaccines intranodally by teaching that “administration of antigen to the iliac lymph node results in increased T and B cell mediated antigen-specific immune responses over other routes of administration.” Thus, the Examiner alleges, the combination of Hurpin, Hodge, Rice and Lehner renders the instant claims obvious. Applicants respectfully disagree.

Applicants do not believe Rice supplements Hodge and Hurpin, with or without Lehner, to render the instant claims obvious. The Examiner is respectfully reminded that it is her burden to provide evidence in the cited art supporting her contention that there was both a suggestion and a reasonable expectation of success. The Examiner points to Rice at col. 43, lines 43-50, which is reproduced below, as providing the elements missing from Hodge and Hurpin:

A vaccine of the invention can be administered via any parenteral route, including but not limited to intramuscular, intraperitoneal, intraarterial (e.g., hepatic artery) and the like. Preferably, since the desired result of vaccination is to elucidate an immune response to HCV, administration directly, or by targeting or choice of a viral vector, indirectly, to lymphoid tissues, e.g., lymph nodes or spleen. Since immune cells are continually replicating, they are an ideal target for retroviral vector-based nucleic acid vaccines, since retroviruses require replicating cells.

However, this is the extent of Rice’s disclosure as to vaccines; the remainder of the document relates to cloning of HCV genes. Rice simply provides the skilled artisan with a laundry list of possible routes of administration, and nothing more. At most, Rice extends to the skilled artisan an invitation to try direct administration by mentioning it, but this does not satisfy the reasonable expectation of success requirement.

Rice’s laundry list is not bolstered by Lehner. The Examiner alleges that Lehner provides the motivation by showing “administration of antigen to the iliac lymph node . . .” (emphasis added). Applicants’ respectfully maintain that the Examiner’s characterization of Lehner is incorrect. Lehner’s method merely teaches a “subcutaneous immunization technique” to “administer vaccine in the proximity of the internal and external iliac lymph nodes” (see Lehner at p. 5489, col. 2; emphasis added). Lehner discloses yet another possible route of administration (in the proximity of but not into a lymph node) and does nothing to cure the deficiencies of Rice. It was not until

Applicants provided their disclosure that the skilled artisan had any reasonable expectation of success. Thus, Applicants maintain that Lehman adds nothing to Rice, Hurpin and / or Hodge, either separately or in combination with one another.

Applicants disagree with the Examiner and believe that Rice does nothing to suffice the deficiencies of Hurpin, Hodge, and / or Lehner. As such, Applicants do not believe the cited references, alone or in combination, render the instantly claims obvious. Accordingly, Applicants respectfully request that this rejection be withdrawn.

B. REJECTION OF CLAIMS 18-19

Claims 18-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hurpin in view of Hodge, Lehner, Rice, Zaremba, and Salgaller. Applicants have carefully reviewed this Office Action and respectfully disagree with the Examiner's conclusions. As the Examiner has not clearly identified the factual foundation for a reasonable expectation of success in the cited art, Applicants respectfully submit that the Examiner has failed to make out a prima facie allegation of obviousness under 35 U.S.C. § 103, as indicated below.

The Examiner alleges that Hurpin teaches intrasplenic administration of an antigen and Hodge teaches a prime-boost immunization methodology, but admits that “. . . neither . . . specifically teaches the administration of the antigen to the lymph node or directly into the lymph node.” The Examiner then turns to Rice to satisfy the deficiencies of Hurpin and Hodge, stating that Rice teaches “. . . that many routes of administration can be used to administer protein or nucleic acid antigens to a mammal in order to induce an immune response, one preferable route being direct administration into lymph nodes” The Examiner also alleges that Lehner provides the motivation to administer vaccines intranodally by teaching that “administration of antigen to the iliac lymph node results in increased T and B cell mediated antigen-specific immune responses over other routes of administration.” Thus, the Examiner alleges, the combination of Hurpin, Hodge, Rice and Lehner renders the instant claims obvious. Applicants respectfully disagree.

Applicants do not believe Rice supplements Hodge and Hurpin, with or without Lehner, to render the instant claims obvious. The Examiner is respectfully reminded that

it is her burden to provide evidence in the cited art supporting her contention that there was both a suggestion and a reasonable expectation of success. The Examiner points to Rice at col. 43, lines 43-50, which is reproduced below, as providing the elements missing from Hodge and Hurpin:

A vaccine of the invention can be administered via any parenteral route, including but not limited to intramuscular, intraperitoneal, intraarterial (e.g., hepatic artery) and the like. Preferably, since the desired result of vaccination is to elucidate an immune response to HCV, administration directly, or by targeting or choice of a viral vector, indirectly, to lymphoid tissues, e.g., lymph nodes or spleen. Since immune cells are continually replicating, they are an ideal target for retroviral vector-based nucleic acid vaccines, since retroviruses require replicating cells.

However, this is the extent of Rice's disclosure as to vaccines; the remainder of the document relates to cloning of HCV genes. Rice simply provides the skilled artisan with a laundry list of possible routes of administration, and nothing more. At most, Rice extends to the skilled artisan an invitation to try direct administration by mentioning it, but this does not satisfy the reasonable expectation of success requirement.

Rice's laundry list is not bolstered by Lehner. The Examiner alleges that Lehner provides the motivation by showing "administration of antigen to the iliac lymph node . . ." (emphasis added). Applicants' respectfully maintain that the Examiner's characterization of Lehner is incorrect. Lehner's method merely teaches a "subcutaneous immunization technique" to "administer vaccine in the proximity of the internal and external iliac lymph nodes" (see Lehner at p. 5489, col. 2; emphasis added). Lehner discloses yet another possible route of administration (in the proximity of but not into a lymph node) and does nothing to cure the deficiencies of Rice. It was not until Applicants provided their disclosure that the skilled artisan had any reasonable expectation of success. Thus, Applicants maintain that Lehman adds nothing to Rice, Hurpin and / or Hodge, either separately or in combination with one another.

The Examiner alleged that Zaremba teaches a modified CEA peptide and that Salgaller teaches a modified gp100 peptide. The Examiner also alleged that the combination of Hurpin, Hodge, Lehner and Rice with Zaremba and Salgaller renders claims 18 and 19, respectively, obvious. Applicants respectfully disagree. For the reasons stated above, Applicants do not believe the Examiner has presented a proper

obviousness rejection of base claims 1 and 17 based on Hurpin, Hodge, Lehner and Rice. The obviousness rejection of claim 18 or 19 requires a proper obviousness rejection of the parental claims, which has not been made. The combination of Zaremba and/or Salgaller with Hurpin, Hodge, Lehner and / or Rice does nothing to cure the deficiencies of the rejection of base claims 1 and 17. Thus, the rejection of claim 18 based on Hurpin, Hodge, Lehner, Rice, and Zaremba and claim 19 based on Hurpin, Hodge, Lehner, Rice, and Salgaller is improper. As such, Applicants respectfully request that this rejection be withdrawn.

C. REJECTION OF CLAIMS 21-27

Claims 21-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hurpin, Hodge, Lehner, and Rice, and further in view of Barnett, et al. Applicants have carefully reviewed this Office Action and respectfully disagree with the Examiner's conclusions. As the Examiner has not clearly identified the factual foundation for a reasonable expectation of success in the cited art, Applicants respectfully submit that the Examiner has failed to make out a prima facie allegation of obviousness under 35 U.S.C. § 103, as indicated below.

The Examiner alleges in her rejection of parental claim 1 that Hurpin teaches intrasplenic administration of an antigen and Hodge teaches a prime-boost immunization methodology, but admits that "... neither ... specifically teaches the administration of the antigen to the lymph node or directly into the lymph node." The Examiner then turns to Rice to satisfy the deficiencies of Hurpin and Hodge, stating that Rice teaches "... that many routes of administration can be used to administer protein or nucleic acid antigens to a mammal in order to induce an immune response, one preferable route being direct administration into lymph nodes" The Examiner also alleges that Lehner provides the motivation to administer vaccines intranodally by teaching that "administration of antigen to the iliac lymph node results in increased T and B cell mediated antigen-specific immune responses over other routes of administration." Thus, the Examiner alleges, the combination of Hurpin, Hodge, Rice and Lehner renders the instant claims obvious. Applicants respectfully disagree.

Applicants do not believe Rice supplements Hodge and Hurpin, with or without Lehner, to render the instant claims obvious. The Examiner is respectfully reminded that it is her burden to provide evidence in the cited art supporting her contention that there was both a suggestion and a reasonable expectation of success. The Examiner points to Rice at col. 43, lines 43-50, which is reproduced below, as providing the elements missing from Hodge and Hurpin:

A vaccine of the invention can be administered via any parenteral route, including but not limited to intramuscular, intraperitoneal, intraarterial (e.g., hepatic artery) and the like. Preferably, since the desired result of vaccination is to elucidate an immune response to HCV, administration directly, or by targeting or choice of a viral vector, indirectly, to lymphoid tissues, e.g., lymph nodes or spleen. Since immune cells are continually replicating, they are an ideal target for retroviral vector-based nucleic acid vaccines, since retroviruses require replicating cells.

However, this is the extent of Rice's disclosure as to vaccines; the remainder of the document relates to cloning of HCV genes. Rice simply provides the skilled artisan with a laundry list of possible routes of administration, and nothing more. At most, Rice extends to the skilled artisan an invitation to try direct administration by mentioning it, but this does not satisfy the reasonable expectation of success requirement.

Rice's laundry list is not bolstered by Lehner. The Examiner alleges that Lehner provides the motivation by showing "administration of antigen to the iliac lymph node . . ." (emphasis added). Applicants' respectfully maintain that the Examiner's characterization of Lehner is incorrect. Lehner's method merely teaches a "subcutaneous immunization technique" to "administer vaccine in the proximity of the internal and external iliac lymph nodes" (see Lehner at p. 5489, col. 2; emphasis added). Lehner discloses yet another possible route of administration (in the proximity of but not into a lymph node) and does nothing to cure the deficiencies of Rice. It was not until Applicants provided their disclosure that the skilled artisan had any reasonable expectation of success. Thus, Applicants maintain that Lehman adds nothing to Rice, Hurpin and / or Hodge, either separately or in combination with one another. Thus, the rejection of parental claim 1 is improper.

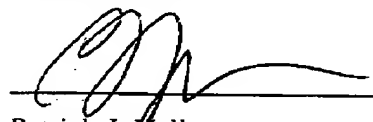
In rejecting claims 21-27, the Examiner alleged that Barnett teaches a prime-boost immunization protocol and that the instantly claimed invention would have been obvious

based on the combination of Hurpin, Hodge, Lehman and Rice. Applicants respectfully disagree. The Examiner has not provided a proper prima facie case of obviousness based on Hurpin, Hodge, Lehman and / or Rice for parental claim 1, for the reasons described above. Barnett demonstrates only intramuscular and epidermal immunizations and is completely silent as to direct administration into a lymph node. At best, combining the cited art provides only an invitation to try a prime-boost protocol, but this is not the standard for a proper obviousness rejection. Thus, the Examiner has simply failed to demonstrate that the skilled artisan would have had any reasonable expectation of success in practicing the claimed invention after reviewing the cited art. Applicants respectfully maintain that the Examiner's rejection of claims 21-27 is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSIONS

Consideration and entry of this amendment is respectfully requested. Applicants respectfully maintain that claims 1, 2 and 4-27 are now in condition for allowance and request that a Notice of Allowance for the pending claims. If the Examiner has any questions or believes a discussion would expedite prosecution, she is encouraged to contact the undersigned at 610-577-6667.

Respectfully submitted,



Patrick J. Halloran
Reg. No. 41, 053

Date: November 7, 2005